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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,746	02/18/2004	Sheldon B. Greer	2954-128	2050
6449	7590	04/30/2007	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C.			ANDERSON, JAMES D	
1425 K STREET, N.W.			ART UNIT	
SUITE 800			PAPER NUMBER	
WASHINGTON, DC 20005			1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/30/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/30/2007.

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PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/779,746	Applicant(s) GREER, SHELDON B.	
	Examiner James D. Anderson	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-24, 28-33 and 39-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24, 28-33 and 39-59 is/are rejected.
- 7) ☒ Claim(s) 24 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1 sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Informalities

Receipt is acknowledged of Applicant's arguments and amendments filed 2/26/2007.

Applicant's arguments, see response and affidavits, filed 2/26/2007, with respect to the rejection(s) of claim(s) 22-42 under 35 U.S.C. § 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Applicant's amendments to the claims and upon further consideration of the limitation "attached to a monoclonal antibody" as recited in claims 29, 31, 39 and 41.

Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn.

Status of the Claims

Claims 22-24, 28-33 and 39-59 are currently pending and are the subject of this Office Action.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 2/26/2007.

Examiner has considered the references cited therein to the extent that each is a proper citation.

Please see attached USPTO Form 1449.

Claim Objections

Claims 24 and 42 objected to because of the following informalities: “deoxycitidine” appears to be misspelled. The correct spelling is ---deoxycytidine--- as found elsewhere in the claims and specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-24, 28-33 and 39-59 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 22 and 32 recite the limitation wherein 5-chloro-2'-deoxycytidine and tetrahydrouridine are administered to a patient. The claims recite “in an effective amount”. However, it is unclear if the effective amount, which is effective to sensitize a patient to radiation, refers to 5-chloro-2'-deoxycytidine or tetrahydrouridine or both agents. If it is Applicant's intent that the effective amount refer to both agents, amending the claims to recite “...in effective amounts...” will overcome this rejection.

Claims 22-24, 28-33 and 39-59 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 22 and 32 recite the limitation wherein “none of PALA, FdC, 4-N-methyl FdC and FdU is administered to the patient”. The claims are indefinite because these abbreviations have not been defined in the claims. The first instance an

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abbreviation is recited in the claims, it is appropriate to recite the expanded name first with the abbreviation in parentheses so as to be clear what subsequent use of the abbreviation means.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 31, 39 and 41 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description Rejection.

The claims are drawn to radionuclides “attached to a monoclonal antibody”. The specification discloses that this is a “theoretical approach” (page 16). The specification does not disclose any monoclonal antibodies or radionuclides attached to monoclonal antibodies as broadly encompassed in the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is a recitation of "monoclonal antibody". Accordingly, in the absence of sufficient

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recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Although drawn to the DNA arts, the findings in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and *Enzo Biochem, Inc. v. Gen-Probe Inc.* are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in *Lilly*. The court stated that, "[A] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials." *Lilly* at 1567, 43 USPQ2d at 1405. The court also stated that:

"[A] generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." *Id.* at 1568, 43 USPQ2d at 1406.

The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.*

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.*

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The *Enzo* court adopted the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Id.* at 1324, 63 USPQ2d at 1613 (emphasis added, bracketed material in original).

While the inventions at issue in *Lilly* and *Enzo* were DNA constructs *per se*, the holdings of those cases are also applicable to claims such as those at issue here (which are drawn to monoclonal antibodies). The instant specification may provide an adequate written description of monoclonal antibodies suitable for the claimed invention, per *Lilly*, by structurally describing representative monoclonal antibodies (*e.g.*, specific amino acid sequences, etc.), or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per *Enzo*, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe monoclonal antibodies useful in the claimed invention in a manner that satisfies either the *Lilly* or *Enzo* standards. Although the specification states that monoclonal antibodies can be used, this does not provide a description of

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the broadly claimed monoclonal antibodies that would satisfy the standard set out in *Enzo* because the specification provides no functional characteristics coupled to structural features (*i.e.*, what amino acid sequences, for example, make up the claimed monoclonal antibodies). Further, the specification also fails to describe monoclonal antibodies by the test set out in *Lilly* because the specification does not describe any specific monoclonal antibodies. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of monoclonal antibodies that is required to practice the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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James D. Anderson, Ph.D.
Patent Examiner
AU 1614

April 19, 2007



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PRIMARY EXAMINER